REMARKS

This Amendment is submitted in reply to the Non-Final Office Action mailed on December 11, 2008. There are no fees due herewith this Amendment. The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-701 on the account statement.

Claims 1-21 are pending in the application. In the Office Action, Claims 1-21 are rejected under 35 U.S.C. 103(a). In response, Claims 1, 5, 14 and 16-17 have been amended and Claims 2-4 have been canceled without prejudice or disclaimer. The amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-6, 9 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,306,908 to Carlson et al. ("*Carlson*") in view of U.S. Patent No. 5,902,578 to Halpin-Dohnalek et al. ("*Halpin-Dohnalek*"). Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Carlson* in view of *Halpin-Dohnalek* and further in view of Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata et al. ("*Ogata*"). Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Carlson* in view of *Halpin-Dohnalek* and further in view of EP 0904784 to Van Hoey-De-Boer et al. ("*Van Hoey-De-Boer*"). Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Carlson* in view of *Halpin-Dohnalek* and further in view of *Van Hoey-De-Boer* and *Ogata*. Claims 11-13 and 17-21 rejected under 35 U.S.C. 103(a) as being unpatentable over *Carlson* in view of *Halpin-Dohnalek* and further in view of U.S. Patent No. 6,777,391 to Kratky et al. ("*Kratky*"). In view of the claim amendments and/or for at least the reasons set forth below, Applicants respectfully disagree and request that the rejection be withdrawn.

Currently amended independent Claim 1 recites, in part, infant or follow-on formulas comprising ARA and DHA, the DHA content is between 0.2 and 0.5% of total fatty acids in the lipid source. Currently amended independent Claims 14 and 16-17 recite, in part, methods comprising administering to an infant an infant or follow-on formula comprising ARA and DHA, the DHA content is between 0.2 and 0.5% of total fatty acids in the lipid source. The

amendments do not add new matter. The amendments are supported in the specification at, for example, page 4, line 19-page 5, line 2. Applicants have surprisingly found that feeding infants the formula of the present invention generally results in the promotion of the immune defenses of the infant, as has been demonstrated by an enhanced response to vaccinations and/or improved gut barrier function and lower levels of intolerance of cows' milk protein coupled with satisfactory physical development. These results are summarized in Examples 1 and 2 of the specification where infants fed a formula of the present invention were compared to infants fed a similar formula but without probiotics. See, specification, Examples.

Applicants are attaching hereto as Exhibit A, the methodology and trials for certain *in vitro* testing of certain exemplary compositions of the presently claimed invention. Specifically, Applicants have performed *in vitro* testing of compositions including ARA, DHA and *Lactobacillus paracasei* NCC 2461 (ST11). While *Lactobacillus paracasei* was selected for the present *in vitro* studies, Applicants submit that the presently claimed subject matter should not be limited to this probiotic. Generally, in the *in vitro* study, T84 cells were incubated overnight in serum free DMEM/F12 followed by a two hour pre-incubation with ST11 cells in the presence or absence of DHA/ARA. After the two hour pre-incubation, *Clostridium difficile* toxin A was added to the apical chamber. After an overnight incubation, transepithelial electrical resistances (TEER) were measured, and the protection of ingredients alone, and in combination, were measured. The results of the test indicate that a combination of a probiotic and DHA/ARA provides better results than either ingredient alone. See, Exhibit A. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every element of the present claims and submit that skilled artisan would have no reason to combine the cited references because the cited references teach away from each other and the present claims.

Carlson, *Halpin-Dohnalek*, *Ogata*, *Van Hoey-De-Boer* and *Kratky* all fail to disclose or suggest infant or follow-on formulas comprising ARA and DHA, wherein the DHA content is between 0.2 and 0.5% of total fatty acids in the lipid source as is required, in part, by the present claims. The Patent Offices cites *Carlson* as teaching DHA. See, Office Action, page 4, lines 4-5. However, the Patent Office also states that "[i]t is unclear if the DHA content is between 0.2 and 0.5% of the total fatty acids in the lipid source however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the DHA amounts to produce

known effects that would be known to one of ordinary skill in the art for the intended application, since it has been held that discovering an optimum value of a result effective variable involvcs only routine skill in the art." See, Office Action, page 4, lines 4-11. Applicants respectfully disagree.

At no place in the disclosure does *Carlson* even mention that any fatty acid may be a certain percentage of the total fatty acids in the lipid source, let alone that DHA is present in the amount of from about 0.2 to 0.5% of the totally fatty acids as is required, in part, by the present claims. Further, *Carlson* relates to compositions for reducing the incidence of necrotising enterocolitis, which is a life-threatening condition which is generally only a risk factor for infants born prematurely. To address this, *Carlson* proposes to administer ARA and DHA, preferably in the form of phospholipids, as these are believed to be more effective than the triglyceride form. See, *Carlson*, column 2, lines 33-39 and column 2, lines 20-45. However, *Carlson* fails to even mention the promotion of the immune system.

Halpin-Dohnalek, *Ogata*, *Van Hoey-De-Boer* and *Kratky* all fail to remedy the deficiencies of *Carlson*. For example, the Patent Office cites *Halpin-Dohnalek* for disclosing probiotics for use in an infant formula, see, Office Action, page 3, lines 13-14; *Ogata* for disclosing Bifidobacterium longum BB536, see, Office Action, page 8, lines 9-10; *Van Hoey-De-Boer* for disclosing lactobacillus rhamnosus GG, see Office Action, page 9, lines 8-9; and *Kratky* for disclosing sweet whey proteins that have been modified by the removal of CGMP from protein, see, Office Action, page 12, lines 7-8. Indeed, none of these references disclose or even suggest infant or follow-on formulas comprising ARA and DHA, wherein the DHA content is between 0.2 and 0.5% of total fatty acids in the lipid source as is required, in part, by the present claims. Accordingly, *Halpin-Dohnalek*, *Ogata*, *Van Hoey-De-Boer* and *Kratky* all fail to remedy the deficiencies of *Carlson*.

Applicants also respectfully submit that the skilled artisan would have no reason to combine the cited references because the cited references teach away from the present claims and from each other. For example, and as discussed above, *Carlson* is entirely directed compositions for reducing the incidence of necrotising enterocolitis, which is a life-threatening condition which is generally only a risk factor for infants born prematurely. To address this, *Carlson* proposes to administer ARA and DHA, preferably in the form of phospholipids, as these are

believed to be more effective than the triglyceride form. See, *Carlson*, column 2, lines 33-39 and column 2, lines 20-45. *Carlson* fails to even mention the promotion of the immune system.

Halpin-Dohnalek is entirely directed toward the use of a mixture of three different probiotic bacterial species including a *Lactobacillus reuteri*, a *Lactobacillus acidophilus* and a *Bifidobacterium infantis* to prevent infectious diarrhea. See, *Halpin-Dohnalek*, Abstract. *Halpin-Dohnalek* teaches that the presence of all three of these strains is necessary to achieve the desired result. See, *Halpin-Dohnalek*, column 4, lines 57-60. Although mention is made of infant formula, the treatment is primarily directed to older children, as may be seen from the clinical study described at Example II and would not, in fact, be suitable for infants since both *Lactobacillus reuteri* and *Lactobacillus acidophilus* product D(-) lactic acid and their consumption by children under three, in general, and infants, in particular, is not recommended by the World Health Organization. Further, *Halpin-Dohnalek* fails to even mention the promotion of the immune system of infants.

Ogata is entirely directed toward the effects of *Bifidobacterium longum* BB536 yogurt on the intestinal environment of healthy adults. See, *Ogata*, Abstract. Although *Ogata* mentions the use of *Bifidobacterium longum* BB536, the article is entirely directed toward consumption by healthy adults, fails to even mention administration of BB536 to infants to strengthen their immune systems, and would not even be considered by one skilled in the art seeking to improve the immune system of infants.

Van Hoey-De-Boer is entirely related to a nutritional composition containing a minimum of three different probiotic strains with the intention of providing protection against infection all the way along the gastro-intestinal tract, thus obviating the need to identify the type of micro-organism responsible for the infection. See, *Van Hoey-De-Boer*, Abstract. The benefits of such compositions include, for example, therapy or prophylaxis of multiple disorders of the gastrointestinal tract such as IBS, Crohn's disease and cancer of the GI tract. However, *Van Hoey-De-Boer* fails to disclose or even suggest that probiotics may play a useful role in strengthening the immune system of infants.

Kratky is entirely directed toward an infant formula having a low threonine content and whey protein. See, *Kratky*, column 1, lines 4-25. *Kratky* fails to disclose any polyunsaturated

fatty acids ,including ARA and DHA, or any probiotics. Further, *Kratky* fails to disclose or even suggest strengthening the immune system of infants.

Further, Applicants submit herewith as Exhibit B, an article by Kankaanpää, which demonstrates that the skilled artisan would be deterred from combining probiotics and polyunsaturated fatty acids, as is required, in part, by the present claims. Specifically, Kankaanpää states that "[a]s polyunsaturated fatty acids (PUFA) possess antimicrobial properties, they may deter the action of probiotics." See, Exhibit B, Kankaanpää, Abstract. Kankaanpää also states that "physiologically relevant levels of free PUFA may influence the functions of probiotics. Consequently, non-adhered probiotics may be washed out from the gastrointestinal tract and potential health benefits may be compromised." See, Exhibit B, Kankaanpää, page 153. Applicants respectfully submit that the Kankaanpää reference would have discouraged the skilled artisan from combining probiotics and PUFA to arrive at the present claims.

As such, the compositions and methods of the cited references are directed toward completely unrelated products having completely unrelated objectives. Accordingly, the skilled artisan would have no reason to combine the cited references to arrive at the present claims. Indeed, it would be a stretch for the skilled artisan, aimed at stimulating the lipid metabolism in the skin of an animal or human, to arrive at such a result by reviewing the cited references, which have widely varying applications and are directed toward entirely different objectives. Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there exists no reason for the skilled artisan to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicants respectfully submit that what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Applicants also submit that if it were proper for the Patent Office to combine any number of references to arrive at the present claims simply because each reference suggests an element of the present claims, then every invention would effectively be rendered obvious. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Applicants respectfully submit that such a reason is not present in the instant case.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1-21 be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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